# UNNECESSARY CLINICAL TESTS IN OPHTHALMOLOGY

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## ABSTRACT

*Purpose:* To define and discuss unnecessary clinical tests in ophthalmology, review the justifications commonly given by clinicians for obtaining unnecessary clinical tests, and suggest a more rational approach to clinical testing in the future.

*Methods:* The author defines an unnecessary clinical test as a test on a human subject that is unlikely to influence that patient's diagnosis, prognosis, or management or is performed exclusively, primarily, or in large part for research purposes.

*Results:* Examples of clinical tests the author categorizes as unnecessary are tests performed to evaluate a new or nonstandard diagnostic instrument or method; tests performed to evaluate sensitivity, specificity, and predictive value of a new instrument or method; tests obtained to provide images or data for future analysis, presentation, or publication; tests obtained routinely in patients of a certain class or category without regard to the individual's personal characteristics, recent clinical history, or clinical signs; and duplicate tests performed without retrieval and review of recent prior tests of the same types and determination of the quality of and findings revealed by those tests. Several justifications that are commonly given by clinicians for their ordering of unnecessary tests are presented, and each of these justifications is critiqued. The principal problems with unnecessary testing are increased costs of medical care, worsening rather than improvement in patient outcomes, and unethical practice.

*Conclusion:* Unnecessary testing is perhaps an unavoidable aspect of current clinical ophthalmic practice in the United States. In spite of this, clinicians (especially academic ophthalmologists) need to be aware of this issue and take appropriate steps to minimize such testing.

*Trans Am Ophthalmol Soc 2005;103:143-147*

## INTRODUCTION

During my over 25 years in private practice plus my prior years in medical school, internship, ophthalmology residency, and retina-ocular oncology fellowship, I have had the opportunity to observe and study the utilization of many different clinical tests by teachers, supervisors, subordinates, and colleagues in a wide variety of clinical settings. Based on my observations, I am convinced that a large proportion of clinical tests ordered and obtained in this country are unnecessary. In the remainder of this article, I will define and give examples of unnecessary clinical tests in ophthalmology, address the impacts of such tests on patient outcomes and the cost of care, and make some recommendations regarding future clinical testing in patients with ophthalmic disorders.

## METHODS

### DEFINITION

A clinical test or study is unnecessary if its results are unlikely to influence patient diagnosis, prognosis, or management[1,2] or if it is performed exclusively, primarily, or in large part for research purposes.

### EXAMPLES

Examples of tests that would fall into this latter category include the following: (1) any test performed to evaluate a new or nonstandard diagnostic instrument or method (eg, optical coherence tomography, indocyanine green angiography, magnetic resonance imaging, multifocal electoretinography); (2) any test performed to evaluate sensitivity, specificity, and predictive value of a new instrument or method; (3) any test that provides images or data primarily for future analysis, presentation, or publication; (4) any test obtained routinely in patients of a certain class or category without regard to the individual's personal characteristics, recent clinical history, or clinical signs (eg, a standard combination of laboratory tests for patients with posterior uveitis[3,4] or retinal vein occlusion[5]); and (5) any duplicate test obtained without retrieval and review of the recent prior test of the same type and determination of its technical quality and the abnormalities it shows.

## RESULTS

### FREQUENCY

There is no published information on the frequency of unnecessary clinical tests of the types specified above. However, from my experience there is good reason to believe that such tests make up the majority of clinical tests obtained in most patients with ophthalmic disorders.

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### JUSTIFICATIONS

Multiple varied justifications are frequently given by clinicians for their ordering of tests of the types mentioned above. Included among the more common justifications are the following:

- The testing will provide information that may improve the patient's outcome.
- The testing will provide preliminary evidence that may alter future clinical practice or influence the design of future clinical trials.
- The testing will provide practical experience that may prove crucial for a future patient.
- The testing is needed for medicolegal protection.
- The testing is expected to reveal something that will influence diagnosis, prognosis, or treatment of the patient.
- The testing provides images that are necessary for patients' education about their disease and the need for treatment.
- The testing is the correct way to practice.

## DISCUSSION

### CRITIQUE OF FOREGOING JUSTIFICATIONS

All of the foregoing justifications for unnecessary clinical testing are debatable. In the following paragraphs, each of these justifications is critiqued.

- *The testing will provide information that may improve the patient's outcome.*
  This is probably the most frequently offered justification for unnecessary and excessive clinical testing in ophthalmology. In spite of this, evidence in support of this statement is sorely lacking. In fact, virtually all studies that have used valid biostatistical and epidemiologic approaches to evaluate the impact of unnecessary testing on patient care have determined that such testing consistently worsens rather than improves patient outcomes.[1,6-9]
- *The testing will provide preliminary evidence that may alter future clinical practice or influence the design of future clinical trials.*
  This statement may be true. However, the possibility of new findings that could influence future patient care or lead to the design of better clinical trials does not justify performance of an unnecessary test, especially one in which the patient is not informed of the investigational nature of the test and the patient or his or her insurance carrier is asked to pay for the test.[6,10,11]
- *The testing will provide practical experience that may prove crucial for a future patient.*
  Some clinicians justify their use of unnecessary tests by their perceived need to have practical experience with the test and its interpretation prior to its performance and interpretation on a patient with a challenging differential diagnosis. In my opinion, physicians who wish to employ a new or unproven clinical test should obtain their experience with that test in a sponsored clinical study prior to the introduction of the test into routine practice and not by testing patients in routine practice without telling them the truth about the reason for that testing.
- *The testing is needed for medicolegal protection.*
  Many physicians obtain unnecessary diagnostic clinical tests to reduce their perceived malpractice liability risk. Surprisingly, however, available evidence about the impact of unnecessary clinical testing on reducing medical malpractice liability does not support this justification.[1,6,9]
- *The testing is expected to reveal something that will influence diagnosis, prognosis, or treatment of the patient.*
  This justification assumes that the physician can make reasonable estimates of the sensitivity and specificity of the clinical test and the prevalence of the disease in the at-risk population. In fact, multiple studies indicate that clinicians frequently overestimate disease frequency[12] and poorly estimate test performance in clinical practice.[13-17] Because of such misestimations, physicians frequently believe the tests they order to be substantially more useful to the patient than they actually are.
- *The testing provides images that are necessary for patient education about their disease and the need for treatment.*
  Many ophthalmologists obtain unnecessary tests to provide images for patient education that they believe are extremely important, if not indispensable, for proper patient care. No objective data exist to either confirm or refute this belief. However, it is difficult to understand that a patient could not be adequately informed about his or her diagnosis and the need for treatment by means of standard images showing the classic features of his or her condition.
- *The testing is the correct way to practice.*
  Many physicians believe that the clinical testing they recommend in a particular patient or setting is correct and appropriate.[18] The beliefs these individuals espouse are frequently irrational, unrealistic, and almost always nonverifiable. In this sense, they are similar to religious beliefs.[19] Indeed, one of my former residents referred to this belief system of ophthalmologists as the "religion of ophthalmology." The belief that whatever tests are ordered by the physician are appropriate seems to be particularly pervasive among clinicians who work in referral centers and teaching institutions. These individuals also often

state that their patients and the referring doctors expect them to do more testing than that which was obtained by the primary ophthalmologist or referring physician.[1,11] They also frequently indicate that a wide battery of tests is necessary for the sake of completeness of the diagnostic workup.[13]

## ADVERSE CONSEQUENCES OF UNNECESSARY DIAGNOSTIC TESTING

There are at least three adverse consequences of obtaining unnecessary diagnostic clinical tests. These consequences are (1) increased costs of health care, (2) worsening of patient outcomes, and (3) unethical practice.

Unnecessary clinical testing substantially increases health care costs.[1,6,10,11,20] Increased costs of health care attributable to unnecessary testing are particularly problematic when physicians have a "perverse financial incentive" to order and obtain unnecessary tests from which they profit financially.[1,9,10]

Unnecessary testing worsens rather than improves patient outcomes.[1,7-9] Although there is a commonly held belief that "more testing is always better,"[1,6] multiple studies employing different methods of data analysis consistently show that excessive clinical testing leads to additional follow-up testing and unnecessary interventions ("cascade effect"[1]) that in aggregate exceed any beneficial impacts of that testing.

Unnecessary testing is unethical because it constitutes research on patients who are not informed of this fact. All patients deserve to be advised about the true reason a test is being ordered and not given false information about the reason or reasons.

What recommendations can one make regarding unnecessary testing? The simplistic answer is "Don't order or obtain any unnecessary clinical tests." Order only those tests that are likely to influence diagnosis, prognosis, or management of the individual patient, and make the decision about the need for specific tests on the basis of a thorough clinical history and an appropriate ophthalmic physical examination plus knowledge of the sensitivity and specificity of the test and not on considerations about perceived malpractice liability, desire to do a complete workup, desire by the patient or referring physician for more testing, or desire to eliminate diagnostic uncertainty.[1] As indicated by Kazon,[2] "Patients should receive—and they and their insurers should pay for—only those tests that are necessary for their care."

But a recommendation that all unnecessary diagnostic clinical testing be avoided is clearly unrealistic. As pointed out by DeKay and Asch,[6] "some defensive clinical testing will persist as long as physicians perceive their liability risk to be non-zero." What we need to do is order only the tests we truly believe are appropriate on the basis of our training, clinical experience, and judgment. If some of these tests are unnecessary, we need to inform the patients of the investigational nature of that testing and obtain their informed consent before proceeding with the testing. In addition, we need to arrange to pay for the unnecessary tests in consenting patients with grant funds, operating revenues, or the clinician's personal financial reserves and not by billing the patients or their insurers.

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## PEER DISCUSSION

DR GEORGE B BARTLEY. This is a thoughtful and provocative paper. After multiple readings, I was able to identify only a few minor suggestions for improvement.

First, the definition of an unnecessary test did not specifically include those that are obtained in the hope (typically futile) of minimizing legal liability. However, defensive medicine was listed as one of the justifications that physicians cite to explain why they order some studies and procedures.

Second, the author questions whether obtaining a "standard combination of laboratory tests" for patients with specific diagnoses is appropriate. Rather, it is recommended that we order tests based on our "training, clinical experience, and judgment." Although these three elements --- formal education, practical experience, and prudent decision-making --- are necessary, they are not sufficient to fulfill the criteria for evidence-based medicine, a term that I was unable to find in the manuscript. Certainly, reflexive ordering of a battery of negligibly relevant tests has little value, but evidence-based clinical pathways and disease management protocols - which frequently include specific laboratory tests - are to be commended and should be followed, whenever germane. I have little doubt that the author endorses and practices evidence-based medicine, but I would have preferred to see the concept promoted more explicitly in his paper.

A third suggestion is similar, i.e., an admonition to state more directly and forcefully that clinical testing can cause considerable harm to patients, rather than simply noting that testing may "worsen patient outcomes." The risks of angiography, radiographic studies that use intravenous contrast agents, and magnetic resonance imaging in the presence of implanted magnetic metal are well known to us all.

The author notes that "there is no published information on the frequency of unnecessary clinical tests" of the categories he describes. I had hoped that this manuscript might fill that void, but the paper is more an editorial than a traditional study as evidenced by the appearance no less than four times of phrases such as "in my opinion," "based on my observations," and "from my experience." Furthermore, numeric data are absent save for assertions that "the majority" and "a large proportion" of clinical tests are unnecessary. Now that the author has piqued our interest, a follow-up study quantifying the true frequency of inappropriate tests would be of great interest and value.

I'll conclude with my own editorial: two simple guidelines for determining whether a clinical test --- or clinical care in general --- is appropriate. They are "all and only" and "my momma."

"All and only" means that we should strive to provide *all* the care that is necessary for our patients, but *only* the care that is necessary. "My momma" is a shorthand reference to the idea that we should care for patients as if they were a close relative, but a relative who does not have health care insurance. The spirit of these guidelines is consistent with the theme of Dr Augsburger's excellent and stimulating paper.

DR RICHARD P. MILLS. You mentioned sensitivity and specificity as a criterion for deciding whether a test should be ordered. From a statistician's point of view, the positive predictive value of a test is what you are really referring to. With Bayes Theorum we combine our prior knowledge of a patient's likelihood of disease from the physical exam and so forth, and then add to it a likelihood ratio that the test involved will improve matters and come out with a post-test probability. That is the kind of clinical thinking we are trying to promote.

DR IRENE H. LUDWIG. I'm concerned that this paper could invite regulators and insurance companies to further restrict and regulate our practices, therefore increasing costs. This could inhibit creative thinking about a disease, especially if someone has a novel idea. If you are outside an institution that has a defined protocol studying this disease you will not be able to order the test, therefore restricting creativity. Restrictive preferred practice protocols can dampen new findings from the outside clinical community, which is often where new ideas will originate.

DR EDWARD L. RAAB. I am in great sympathy with your views and also with the very cogent of your discussant. You might add to your list of unnecessary testing those which give duplicative information with no more degree of confidence than the ones already obtained, whether or not they are invasive. I would also suggest adding unnecessary consultation. An example would be a request for an evaluation of whether a patient with unequivocally documented subacute bacterial endocarditis has retinal hemorrhages. That piece of information would take the case absolutely no further, in my view. Another comment has to do with defensive of medicine. The standard to which we all wish to conform was not developed in a vacuum. The standard evolves from our own behavior. If our own behavior is inappropriate, by conforming we may be solidifying what is inappropriate. Defense (uncritically conforming) is not the best offense; sometimes it's the worst offense.

DR RICHARD L. LINDSTROM. One of the most glaring examples of inappropriate testing in ophthalmology is the medical preoperative testing of the cataract patient. If we look at the typical cataract patient who comes to surgery at 70 and is healthy, almost all of our institutions require a complete physical examination including blood work, electrocardiogram, etc. This probably adds about one billion dollars to health care costs. Several good studies have shown that it really has no value in the routine healthy patient,

although it may be indicated in select cases. It is interesting how difficult it is to change that. After the good papers came out, I went to our institution and worked through the system to have this changed; it turned out that the tradition was so strong, that it was impossible. The major institutions continue to require it and then when you have your own ambulatory surgery center you feel as if you are outside the standard of care if you choose not to do it. This process will be very difficult to change. Cataract surgery is probably the place where we should start eliminating testing because there is a huge expense and it's clear that it has no value.

DR D. JACKSON COLEMAN. You made some very sweeping statements about tests that really relate to the development of new technologies. Without testing, there would be no OCT, ultrasound, MRI or perhaps even photographs. I think what you were saying was that there should not be unnecessary charging. Patients should not be billed for something that's experimental or something that is being developed and of course, the patient should be fully informed. If that is your real message then I think you're absolutely correct. But, initially you pointed out that there should be no testing if it was only to develop a new technique or to determine the sensitivity or specificity. Please clarify if it was really the financial and ethical issues or if you are really referring to any new tests.

DR MICHAEL J. ELMAN. I had hoped that the manuscript would be more data-driven. It might be beneficial to reframe the question as to whether it was unnecessary as to who pays for it. I've been involved in a number of clinical trials, many of which have been sponsored by the NIH and some of them from private industry. In almost all of those trials, tests that are routinely performed, and which you may make the argument are unnecessary, had been paid for by the sponsor, and not by the patient or their insurance company. They are necessary for the study and one might argue perhaps are necessary for the patient's care and ultimately to the benefit of society, but in fact they are not paid for by the patient or their insurance company. With the evolution of the more stripped down trials the design is evolving to what the usual and customary care that occurs in the community reflects. There has been some very healthy discussion of the refusal by principal investigators to perform tests and charge them to patients if they are not in fact part of the usual and customary care. That discussion is ongoing, and I'd like to hear your comments on that as well.

DR RALPH C. EAGLE JR. Please comment on the role of testing and medical education.

DR GEORGE L. SPAETH. Around the middle of the First Millennium the Japanese swordmaster, Musashi Miyamoto, wrote "*The Book of Five Rings*,"[1] about swordplay. He advised, "Do nothing unnecessary." That comment has stayed with me since I read it some 20 years ago. Its corollary is, "Do only what is necessary." Musashi's comment has made me think, as your talk has made many people think.

Is gonioscopy unnecessary when one does not suspect an abnormality of the anterior chamber angle? I maintain that it is necessary to gonioscope thousands of patients in whom you expect no benefit to the person being gonioscoped. It is necessary to do this because one cannot recognize pathology until one knows what is normal, and it is necessary to examine thousands of normal angles to learn what is normal versus what is not normal. Furthermore, the angle is invisible without gonioscopy, and one cannot tell what is happening in the angle without performing gonioscopy. My point is that something that may be "unnecessary" for the individual may be essential for a group of individuals. Our job is to help people, and we cannot do that without knowing what we are doing, and we cannot know what we are doing without doing things that are unnecessary. Therefore we must do some unnecessary testing.

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DR ALLAN J. FLACH. A number of individuals have brought up the word "experimentation." Every single patient that we treat, whether it is with surgery or medical treatment, is an experiment. As far as medical treatment is concerned, where do they fit on the bell-shaped curve of a drug response? I think a lot of our unnecessary bureaucratic activity surrounding IRB approvals and surrounding medical/legal issues could be simplified if every single one of us were honest with every single patient and inform them that they are in and of themselves an experiment and that we are going to nurse them through with their help and with our expertise.

DR VICTOR M. ELNER. The paper is provocative and also speaks to the point that we should revisit how we do ophthalmic examinations. Perhaps parts of the ophthalmic examinations are entirely unnecessary, or for that matter, the ophthalmic examination done on an asymptomatic patient might be entirely unnecessary. You're assuming that we already know what is necessary, but perhaps many of the things that we do currently are unnecessary. How should we eliminate a lot of the things we do now?

DR JAMES J. AUGSBURGER. I would like to address one of the major criticisms of my paper that Dr Bartley and several other discussants mentioned: the lack of hard data in support of my thesis. To address this criticism, I'd like to quote from an article by Karen Titus that was published electronically on the College of American Pathologists website in 2001 [www.cap.org/apps/docs/cap_today/cover_stories/cov_0401.html]. According to this author, "Inappropriate testing is a vast and fuzzy proposition, one more often defined by hunches and suspicions than by cold facts. Producing hard evidence of inappropriate testing is a difficult matter. Using that evidence to change physician ordering habits is another one still." It would be nice to get the kind of hard data that Dr Bartley and the other discussants seek. But, in fact, all of us believe that every test **we** order is necessary and appropriate. Because of this, identifying and collecting hard data on the frequency and costs of unnecessary testing are not currently feasible.

Regarding Dr Mills' comment, I mentioned only sensitivity and specificity because most ophthalmologists are more familiar with them than with positive predictive value, negative predictive value, and predictions coming from Bayes Theorem.

Finally, I thank all of the discussants for their pertinent questions and remarks regarding my paper.